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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,235	10/22/2001	Yat Sun Or	ENP-036	3609

36078 7590 04/03/2003

ENANTA PHARMACEUTICALS, INC.  
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WATERTOWN, MA 02472

EXAMINER

ANDERSON, REBECCA L

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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7590 03/05/2003

Sandhya L. Kalkunte  
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Watertown, MA 02472

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\* Restarted time on 4/3/03  
due to address was placed  
in system incorrectly.

B. Gray  
4/2/03

# Office Action Summary

Application No.

10/007,235

Applicant(s)

OR ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 16 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,6,9,10,19-22 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 1,2,4,7,8,11-18 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-24 are currently pending in the instant application. Claims 3, 5, 6, 9 and 10, 19-22 and 24 are withdrawn as being for non-elected subject matter, and claims 1, 2, 4, 7, 8, 11-18 and 24 are objected.

### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-18 and 23 and the election of the species EP 001237 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that restriction is not mandatory and that it would be convenient to examine all the claims (i.e. there is not a serious burden). This is not found persuasive because 35 U.S.C. 121 states that restriction between two or more independent and distinct inventions claimed in one application may be required, and the examiner has properly restricted the independent inventions. In regards to a burdensome search, the inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter, which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

An explanation of the statement, "Upon election of a single disclosed species, a generic concept inclusive of the elected species will be identified by the Examiner for examination along with the elected species," and a response to applicant's references to MPEP 803.02 and lack of unity is that the restriction requirement is made under 35

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U.S.C. 121, which gives the Commissioner (Director) the authority to limit the examination of an application where two or more independent and distinct inventions are claimed to only one invention. The examiner has indicated that more than one-independent and distinct invention is claimed in this application and has restricted (limited) claimed subject matter accordingly. Thus the requirement to restrict the claims in this application is predicated on the fact that the claimed subject matter involves more than one independent and distinct invention. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. In regards to the reference to the lack of unity standard, this standard does not address the premise of the restriction requirement. Notwithstanding that lack of unity is not the basis for this restriction requirement, a lack of unity standard requires that the claims contain a special technical feature that defines a contribution over the art. Here the claims contain a  $\begin{array}{c} \text{N}-\text{C}-\text{C} \\ | \quad | \\ \text{H} \quad \text{OH} \end{array}$ , which does not define a contribution over the art. So, here we have claims which involve more than one independent or distinct inventions. Under 35 U.S.C. 121, the claims may be restricted and the examination limited to a restricted invention. There is no argument or evidence to the contrary. Accordingly, restriction as has been presented in this application is proper.

The requirement is still deemed proper and is therefore made FINAL.

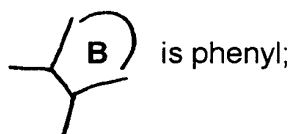
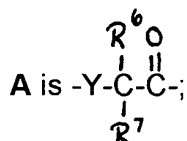
With the identification of the above noted species, the examiner, as indicated in the restriction requirement of Paper No. 2, will identify a generic concept, inclusive of said species, for examination.

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The generic concept is that of the compound as found in claim 1 wherein:

**R1** is chosen from the group consisting of C1-C20 alkyl, substituted C1-C20 alkyl, aryl, alkylaryl, substituted alkylaryl, C3-C10 oxaalkyl and substituted aryl;

**R2** is chosen from the group consisting of C1-C10 hydrocarbon and substituted aryl;



containing from 0 to 3 substituents chosen from lower alkyl, lower alkoxy, lower alkylthio, hydroxy, mercapto, cyano, carboxy, lower alkoxycarbonyl, (lower alkoxycarbonyl)lower alkoxy, lower alkylaminocarbonyl, amino, lower alkylamino, di(lower alkyl)amino, nitro, halo and haloalkyl;

**R5** is chosen from the group consisting of hydrogen, alkyl, aryl and substituted aryl;

**R6** and **R7** are chosen independently from the group consisting of hydrogen, halogen and lower alkyl;

**D** is  $-\text{C}(\text{O})-$  or  $-\text{NHC}(\text{O})-$ ;

**E** is chosen from the group consisting of C5-C8 alkyl and NR10R11;

**R10** is hydrogen or lower alkyl;

**R11** is chosen from C1-C10 hydrocarbon, substituted aryl and substituted alkyl;

and

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Y is -O- .

The remaining subject matter of claims 1, 2, 4, 7, 8, 11-18 and 23 and the subject matter of claims 3, 5, 6, 9, 10, 19-22 and 24 stands withdrawn, 37 CFR 1.142 (b), as being for non-elected inventions. The withdrawn subject matter of the claims is properly restricted as said subject matter differs materially in structure and element from the elected subject matter so as to be patentably distinct, i.e. a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. Additionally, the fields of search are not co-extensive.

Accordingly, the claims are drawn to more than a single invention and restriction as has been required is proper, 37 CFR 1.142 (a). It is noted, however, that if the product claims of invention I are subsequently found allowable (i.e. presented drawn solely to the elected subject matter as indicated supra), the withdrawn method claim, which depends from or otherwise includes all the limitations of the allowable product claims will be rejoined (i.e. group II, claims 19-22).

### ***Claim Objections***

Claims 1, 2, 4, 7, 8, 11-18 and 23 are objected to as containing non-elected subject matter. The claims presented drawn solely to the elected subject matter as indicated supra, would appear allowable.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (703)

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605-1157. Mrs. Anderson can normally be reached Monday through Friday 7:00AM to 3:30PM.

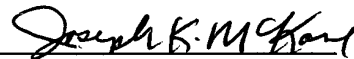
If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone numbers are (703) 308-1235 and (703) 308-0196.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45AM to 4:45PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4242, (703) 305-3592, and (703) 305-3014.



Rebecca Anderson  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600



Joseph McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600